510 (K) Summary
Disc-O-Tech Medical Technologies Ltd.'s Fixion™ Unipolar Modular Hemi-Hip System

MAR 8 2002

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Company Name
Disc-O-Tech Medical Technologies, Ltd.
3 Hasadnaot St. Herzlia, 46728, Israel

Submitter's Name and Contact Person
Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
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Washington, DC 20004
Tel.: 202-637-5794
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Date Prepared
March 6, 2002

Trade/Proprietary Name
Fixion™ Unipolar Modular Hemi-Hip System ("Fixion UH")

Classification Name
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

Predicate Devices
The Fixion UH intended use, materials and accessories are substantially equivalent to those used in Depuy Orthopeadics' Elite® Modular Hip System and S-ROM Total Hip System, as well as Disc-O-Tech's Fixion™ Interlocking PF Intramedullary Nailing System. The Fixion UH is also substantially equivalent to Link America, Inc.'s Link® Reconstruction Hip and to Smith and Nephew's Biolox® Alumina Ceramic Femoral Head.

Performance Standards
The Fixion UH conforms to the requirements of ISO 7206-8 (1995) "Implants for Surgery Partial and Total Hip Joint Prostheses – Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion." The Fixion UH also conforms to FDA Draft Guidance Documents: Guidance Document for Femoral Stem Prostheses (1995) and Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components (1995). In addition, the Fixion UH conforms to FDA Draft Guidance Document for the Preparation of Premarket Notification for Ceramic

Ball Hip Systems (1995).

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Intended Use

The Fixion Unipolar Modular Hemi-Hip System is intended for use for cemented or non-cemented use as a hemi hip replacement in case of:

- Femoral head/neck fractures or non-unions
- Aseptic necrosis of the femoral head/neck
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip, with minimal acetabular involvement

System Description

The Fixion UH is a modular hemi-hip replacement system, which is composed of a metallic femoral and neck part ("stem") with an expandable femoral component and is offered in various dimensions from metal or Alumina ceramic for use during partial hip replacement.

Substantial Equivalence

The Fixion UH System has substantially equivalent intended use and indications for use as the Elite Modular Hip System and the other predicates, *i.e.*, replacement of hips.

The performance characteristics of the Fixion UH have been tested and found to meet the specifications through a series of bench tests.

The Stem of the Fixion UH Unipolar Hemi-Hip System, like the Fixion™ PF Intramedullary Nail, is made of 316LVM Stainless Steel. The cross section of the Fixion UH stem body and the Fixion Interlocking PF Intramedullary nail is identical and circular with reinforcement bars.

Fixation of the Fixion UH Stem to the femur is further enhanced by its inflation with sterile saline similar to the Fixion PF Nail and results in the abutment of the 4 reinforcement bars to the medullary canal wall. Rotational and axial stability is aided by the shape of the Stem Neck. The inflation of the Fixion UH Stem with saline, which is a non-compressible biocompatible fluid, is identical to the cleared Fixion PF Nail and does not raise any new safety and efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Disc-O-Tech Medical Technologies, LTD.
c/o Mr. Johnathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004

Re: K014072
Trade Name: Fixion Unipolar Modular Hemi-Hip System (Fixion UH)
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Date: December 3, 2001
Received: December 10, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(K) Number (if known): K014072

Device Name: Fixion Unipolar Modular Hemi-Hip System (Fixion™ UH)

Indication for Use: The Fixion Unipolar Modular Hemi-Hip System is intended for cemented or non-cemented use as a hemi hip replacement in cases of:

- Femoral head/neck fractures or non-unions
- Aseptic necrosis of the femoral head/neck
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip. with minimal acetabular involvement

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General, Restorative and Neurological Devices

510(k) Number: K014072

Prescription Use X (per 21 CFR 801.109) OR Over the Counter Use ____

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014072